SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: A 52-Week, Phase 3 Study to Evaluate Safety and Biomarkers of Resmetirom (MGL-3196) in Patients with Non-alcoholic Fatty Liver Disease (NAFLD) (MAESTRO-NAFLD-1)

PROTOCOL NO.: MGL-3196-14
IRB Protocol # 20192651

SPONSOR: Madrigal Pharmaceuticals, Inc.

INVESTIGATOR: Anuj Bhargava, MD
1031 Office Park Road
Suite 2
West Des Moines, Iowa 50265
United States

STUDY RELATED PHONE NUMBER(S): 515-329-6800 (24 hours)

PARTICIPATION

You are being asked to participate in a medical research study. Your participation in this research study is up to you, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so that you can make your decision. This form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. You may have a copy of this form to review at your leisure or to ask advice from others.

The study doctor or study staff will answer any questions you may have about this form or about the study. Please read this document carefully and do not hesitate to ask anything about this information. This form may contain words that you do not understand. Please ask the study doctor or study staff to explain the words or information that you do not understand. After reading the form and after you have had a chance to ask questions and have them answered, if you would like to participate in the study, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

BACKGROUND

Non-alcoholic fatty liver disease (NAFLD) includes all types of non-alcoholic fatty liver diseases from simple steatosis (NAFL), an early form of fatty liver disease, to Non-Alcoholic Steatohepatitis (NASH) which is associated with an increased amount of fat and inflammation in the liver and progressive scarring of the liver that may lead to cirrhosis. NAFLD is common in patients with obesity and diabetes, and has increased in prevalence in the United States and around the world in association with the obesity epidemic. The diagnosis of definite NASH is made by taking a small sample of the liver to look at, which is called a liver biopsy. The results of blood tests and imaging studies may also be used to provide confidence that a patient has NAFLD, and a high likelihood that a patient has NASH. Having NAFLD, including the more advanced form, NASH with fibrosis, increases the chances of having heart disease and increases the risk of heart attacks or strokes, especially if your LDL-cholesterol and/or triglycerides are high, a disease called hyperlipidemia. Patients with NAFLD who have diabetes and high blood pressure or who have had a previous heart attack or stroke also have a higher chance of heart disease and risk of heart attacks and strokes.

There are currently no approved medicines to treat NASH or NASH/NAFLD with hyperlipidemia. To reduce cholesterol, some patients take approved medications such as statins or triglycerides such as fish oils but often, patients still have high cholesterol and are not at the recommended blood level of cholesterol or triglycerides even with those medications.

Madrigal Pharmaceuticals, Inc. (the Sponsor of the study) is running this medical research study to learn more about the safety of an experimental test medicine named resmetirom in people with NASH/NAFLD and to see if resmetirom will help in the

treatment of NASH/NAFLD with hyperlipidemia. Resmetirom is an 'investigational' drug, i.e., it is not approved for use by the U.S. Food and Drug Administration (FDA). Resmetirom was previously tested in a 9-month study in 125 patients with NASH and was found to be well-tolerated with some cases of diarrhea, and caused a decrease in the amount of fat in the liver, and caused a decrease in NASH compared with patients taking placebo (a placebo looks like the investigational drug but does not contain any of the active ingredients of the investigational drug, i.e., "sugar pill"). Resmetirom is currently being tested in a four and a half year-long study in patients with NASH with advanced liver fibrosis.

PURPOSE

You are being asked if you want to participate in this medical research study because you have been diagnosed with NASH/NAFLD using a liver biopsy or are likely to have NASH/NAFLD based on other tests along with high cholesterol, including low density lipoprotein (LDL) or "bad" cholesterol and/or triglycerides that are associated with increased cardiovascular disease such as heart attacks and strokes.

Resmetirom works together with a type of thyroid hormone receptor in the liver to decrease the amount of fat that has built up in the liver and possibly reduce the inflammation and fibrosis that are associated with NASH. Resmetirom also reduces LDL-cholesterol, triglycerides and other lipids that are associated with increased risk of heart attacks and strokes. Resmetirom is an investigational drug. This means that it is still being tested in research studies and that it has not been approved by the FDA for use for the treatment of NASH.

The purpose of this medical research study is to determine:

- The safety of resmetirom compared to placebo in participants with NASH/NAFLD
- How well resmetirom works for the treatment of high LDL-cholesterol compared to placebo in patients with NASH/NAFLD
- How well resmetirom works for the reduction of triglycerides, other elevated lipids, and reduction in liver fat compared to placebo
- If a higher dose and/or a lower dose of resmetirom works better than placebo for participants with NASH/NAFLD
- How well resmetirom works to reduce blood and imaging markers of NASH/NAFLD compared to placebo

STUDY DESIGN

If you agree to take part in this study, you will be one of approximately 800 patients at approximately 75 clinical study sites in North America.

By signing this Consent Form, you agree to take part in the study.

The study is open to male and female participants 18 years of age or older who meet the study requirements. Your study doctor will ask you to come to the clinic for a screening visit to see if you are able to take part in the study.

This is a randomized, double-blind, placebo-controlled study with an open-label arm.

Randomized means the drug you take during your participation in the study will be chosen by chance (like drawing straws): resmetirom 80 mg, or resmetirom 100, or Placebo.

Double-blind means you and your study doctor will not know if you will be taking resmetirom or placebo. Resmetirom and placebo will be supplied to your study doctor by Madrigal Pharmaceuticals Inc., who is the sponsor of this study. Almost all the people involved with the study, including the sponsor, the study nurses, and the study coordinators at the study site, will not know what treatment you are receiving. Only a few individuals directly supplying the study drug will know which patients receive Placebo and which receive resmetirom. Your study doctor can find out in case of an emergency.

Placebo-controlled means that the study results of patients taking resmetirom will be compared to the results of patients taking placebo.

The term “study drug” refers to both resmetirom and placebo in this form.

Approximately the first 30 patients who start the study will receive resmetirom 100 mg in what is called an “open-label arm” meaning the dose and treatment are not blinded. Patients with moderate reduction in kidney function below a certain level will also be in the open-label arm. You and everyone in the open-label arm will know that the dose you are taking is resmetirom 100 mg.

After approximately the first 30 patients start the study, and until a total of approximately 175 patients are enrolled in the open-label group, patients will receive, by chance, either study drug (double-blind resmetirom 80 mg, resmetirom 100 mg, or placebo) or open-label resmetirom 100 mg. If you are not receiving open-label treatment, you will not be told whether you are taking placebo or study drug. If you have moderate reduction in kidney function, you will always be part of the open-label arm and receive resmetirom 100 mg per day.

A group of up to 30 patients with compensated NASH cirrhosis, a condition where the liver is severely scarred, are also eligible to be part of the open-label arm and receive resmetirom 80 mg per day.

Once the open-label group is closed, patients will only receive, by chance, resmetirom 80 mg, resmetirom 100 mg, or placebo. Again, you will not be told what treatment you are taking.

Based on the safety information from the initial group of patients on thyroxine above a dose of 75 mcg per day who were enrolled in the open-label group, patients on thyroxine treatment above 75 mcg per day will be enrolled in the randomized study arms where they will receive, by chance, resmetirom 80 mg, resmetirom 100 mg, or placebo.

STUDY ACTIVITIES AND TIME COMMITMENT

The maximum amount of time you could participate in the study is approximately 15 months. During this time, you will be required to visit the clinic at most 16 times (or 17 times if you are a patient with compensated NASH cirrhosis). First, you will undergo tests to see if you are eligible to take part in the study, which can take up to 8 weeks. This is called the screening period. If you are eligible to take part in the study, you may receive treatment for up to 52 weeks (1 year), and at the end of treatment the study doctor will continue to monitor you for up to 4 weeks. If you complete the study and want to continue taking the study drug, you can receive open-label study drug after you sign consent to continue in an extension study. If you decide to do so, you will receive resmetirom for up to one year and the treatment will not be blinded. Patient safety and efficacy will be monitored similar to the first part of the study.

At your first visit, your study doctor will check to see if you qualify to take part in the study. This will involve completing some procedures and tests, including but not limited to taking some blood and urine samples. If you qualify to take part in the study based on those tests, you will be asked to come back for additional visits and you will have some further procedures and tests performed.

If you are a woman capable of having children, you will be required to have a pregnancy test to make sure you are not pregnant.

To participate in this study, there are several examinations, tests, questionnaires and/or procedures as described below, that will be performed at different times before, during, and after your treatment with resmetirom or placebo and you will be asked to visit your study doctor’s office at various times during the study.

RESPONSIBILITIES

As a patient in this study, you have certain responsibilities. You will have to:

- Complete all required visits to the study site. Tell your study doctor about your upcoming commitments like planned vacations so that your study doctor can let you know whether the clinic visit can be rescheduled.

- Take the study drug as instructed by your study doctor and keep the study drug out of the reach of children or persons with limited ability to read and understand.
- Tell the study doctor your full medical history.
- Tell the study doctor of any side effects and changes or new medical problems you suffer during the study.
- Tell the study doctor if you (or your partner) become pregnant.
- Tell your study doctor if you plan to have any surgery or any other medical treatment or medical procedure.
- You are not allowed to take certain medications and herbal/ natural supplements while in this study. Your study doctor will review your current medications and herbal/ natural supplements with you to determine if they are allowed to be taken while participating in this study. Before starting any new medications or herbal/ natural supplements while participating in this study, you must consult with the study doctor first.
- Complete questionnaires.
- You must bring back all unused study drug and all study drug containers (even if they are empty or used).
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.
- Some insurance companies require people who are renewing a policy or getting a new policy to tell them about participating in a clinical study. You should check with your insurer to determine if taking part in this study will affect your existing insurance policy.

PROCEDURES
This study consists of 3 periods:

- Screening Period (up to 8 weeks)
- Study Drug Period (52 weeks)
- Follow Up Period (4 weeks)

After the Study Drug period is done, you will be asked to return to the study site after about 28 days for a Follow-Up Visit. If you decide to withdraw or are removed from the study before this time, you will also be asked to return to the study site for additional follow up visits about 28 days and about 3 months after you discontinue from the study so that the study staff can check your health.

Screening Period (Up to 8 weeks):
The purpose of this period is to inform you about the study and to determine if you are eligible to participate in this study.

Screening Visit:
Before any study procedures or tests are started, you will be asked to read and sign this informed consent. The study staff will answer any questions you may have. If you feel and decide you would like to participate in the study, you will complete the Screening Procedures described below to determine if you are eligible to participate.

The Screening Visit can occur up to 8 weeks before you receive the first dose of study drug. The following screening examinations, tests, or procedures will be performed after you have given written consent to participate in this study:

- The study doctor or study staff will ask you about how you have been feeling since your last appointment.
- You will be asked to list all the medications that you are taking, including all medicine prescribed by a doctor and those that you bought on your own without a doctor's prescription (herbals and over-the-counter medications).
- You will be asked about your alcohol consumption and how much you drink
- Your medical history (including substance abuse), will be recorded.
- Your ethnicity, date of birth, age, and gender will be documented.
- A list of study eligibility requirements will be reviewed
- A physical examination will be done which will include vital signs, height, weight, body mass index (BMI), waist circumference, waist-hip ratio, temperature, respiratory rate, resting pulse, and seated blood pressure.
- A 12-lead electrocardiogram (ECG), which records the electrical activity of your heart using electrodes placed on the skin, will be performed.
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood samples will be collected after a 10 hour fast (no food or beverages other than water permitted) for the following:

    - To check your blood counts (numbers of different types of cells in your blood), and for other laboratory tests to check your general health status (blood's ability to clot, liver and kidney function, status of your thyroid gland, blood lipids (like LDL cholesterol) and sugar levels)
    - To test for active Hepatitis B and C (viruses that affect the liver) infection, and HIV (Human Immunodeficiency Virus) which can cause AIDS. If you test positive for HIV, Hepatitis B or C, results will be shared with you and will affect your eligibility to participate as per your doctor's judgement and your medical history. Depending on your location, the study team will be required to report any positive tests to the local health department. If you do not wish to be tested for Hepatitis B, C and HIV, you should not participate in this study.
    - To determine the state of your liver disease
    - If you are a woman who is able to become pregnant, you will have a blood sample collected for a pregnancy test

- Urine sample will be collected for urinalysis (routine laboratory testing) which will be performed for assessing your general health status. Also, a urine drug screening will be completed to see if you test positive for drugs that would exclude you from participation in the study.
- During the screening period, you may need to return to the clinic or clinical laboratory for an additional blood test to confirm a result.

Screening Visit – Special Procedures: **The following special procedures may be done during this period to determine if you qualify to participate in this study:**

- A Fibroscan may be performed if you have not had a qualifying Fibroscan performed within 3 months of consenting for this study. The Fibroscan is a test which is done on the outside of your body and lasts about 10-15 minutes. It helps to show whether your liver is healthy and determine fatty changes in the liver. It may also help determine whether your liver has fibrosis (scarring).
- A Magnetic Resonance Imaging – If your screening blood tests qualify, a Magnetic Resonance Imaging - Proton Density Fat Fraction test also known as MRI-PDFF will be done after the initial screening visit. Exceptions include a recent MRI-PDFF performed within approximately 8 weeks of the expected randomization date, or inability to have the procedure. This is a test that images fat in your liver. In addition, at the same time you have the MRI-PDFF, you may be asked to undergo a Magnetic Resonance Elastography study also known as MRE – a test that measures the stiffness of your liver – and/or a Corrected T1 study also known as cT1 – a test that assesses liver inflammation and fibrosis. All MRI tests will be performed at the same visit.
- A Dual-energy X-ray Absorptiometry, also known as a DXA, scan, which measures the health of your bones will be performed if you qualify for the study based on all of the screening procedures and have been scheduled to enter the Study Drug period of the study. If there are scheduling difficulties, your DXA scan could be performed within approximately 1 week after you receive your first dose of study drug.

Table Summary of Special Procedures Conducted During the Screening Period

Procedure or Test	Description
FibroScan	You might be asked to have a FibroScan which is a type of ultrasound used to measure the amount of stiffness in the liver if you did not have a Fibroscan within 3 months prior to the screening period. You may feel a small amount of pressure from the probe and you will be required not to eat or drink before the assessment.

MRI-PDFF and/or Magnetic Resonance Elastography (MRE) and/or Corrected T1 (cT1)	If your screening blood tests qualify, you will be asked to have a Magnetic Resonance Imaging (MRI) study to measure liver fat and an MRE at the same time that the MRI is performed. The MRI-PDFF measures the amount of fat in your liver, the MRE measures the stiffness of your liver, and cT1 assesses liver inflammation and fibrosis. You will lie on an examination table that slides into an MRI unit (a large, tube-shaped magnet that is open on both ends). For the MRE, a paddle attachment will be wrapped around your waist and sound waves will be sent through your body while you are inside the MRI unit. You will not feel the magnetic field of the MRI machine.
Dual-energy x-ray absorptiometry (DXA scan)	Uses x-ray beams passing through your bones to measure your bone density (how thick your bones are). If all of your other tests qualify for the study, you will undergo a DXA scan at the timeframe indicated in the text above.

Study Drug Period (52 weeks)

All study visits except one, will require you to have been fasting (no food or drink except for water) for at least ten hours prior to the study visit. However, at the Week 8 visit, you are allowed to eat prior to the visit. Also, for all study visits except for Week 8, you will not take your study drug prior to your visit. Be sure to bring your study drug with you because you will be directed to take your study drug at that study visit. For the Week 8 study visit, you will take your study drug 2 to 6 hours before you come for your study visit. You will be provided instructions on when and how to record when you take your study medication. On the day of your study visits, you are allowed to take any other medications that you normally take in the morning with water before the study visit.

In addition, if you have compensated NASH cirrhosis, there is an additional visit at Week 2 for which you will be allowed to eat prior to the visit.

Baseline Visit

During this visit, you will be assigned to a treatment group and will take your first dose of study drug after you finish all of the study procedures.

The following information will be collected, or procedures performed, in addition to the general treatment visit assessments listed below for the Baseline through Week 52 visits:

- Review of all of the study eligibility requirements and procedures
- If you take cholesterol or lipid lowering drugs, you will be asked about the last time you took those medications
- Confirm that you are fasting
- You will be asked to complete some health-related questionnaires about your daily quality of life and your physical and mental well-being
- A 12-lead electrocardiogram (ECG) which records the electrical activity of your heart using electrodes places on the skin, will be performed
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood samples will be collected for the following:

    - To check your heart and liver function
    - To measure biomarkers in your blood (biomarkers are substances in your body that can be used to detect a disease, describe it, or find out how a disease is responding to treatment)
    - Genetic testing (only if you agree to participate and sign the genetic testing section of the Consent Form) to look at the genes that cause NASH or other specific genes which will help to understand how resmetirom (study drug) works
    - To test for alcohol in your blood
    - To check your blood counts (numbers of different types of cells in your blood), and for other laboratory tests to check your general health status (blood's ability to clot, liver and kidney function, status of thyroid gland, blood lipid and sugar levels) before you receive the study drug.

Treatment Visits (Baseline Visit through Week 52 Visit)
The following information will be collected for all treatment visits:

- Confirm that you are fasting (or not fasting during the Week 8 visit, as well as the Week 2 visit for compensated NASH cirrhosis patients only)
- A physical examination will be done which will include vital signs, height, weight, body mass index (BMI), waist circumference, waist-hip ratio, temperature, respiratory rate, resting pulse, and seated blood pressure
- You will be asked about your alcohol consumption and how much you drink
- You will be asked to list all medications that you are taking, including all medicine prescribed by a doctor and those that you bought on your own without a doctor's prescription (herbals and over-the-counter medication)
- If you take cholesterol or lipid lowering drugs, you will be asked about the last time you took those medications
- You will be asked about the last time you took your study medication
- The study doctor or study staff will ask you about how you have been feeling since your last appointment

- You will receive your study drug in the clinic (except for Week 8; see Week 8 visit below)
- You will return the study drug you were taking together with its container and you be given new study drug
- You will have a discussion about your nutrition and exercise habits and ways to maintain a healthy lifestyle
- Blood samples will be collected after a 10 hour fast (no food or beverages other than water permitted: except for Week 8 visit) for the following:

    - To check your blood counts (numbers of different types of cells in your blood), and for other laboratory tests to check your general health status (blood's ability to clot, liver and kidney function, status of thyroid gland, blood lipid and sugar levels)
    - To measure, at selected visits, biomarkers in your blood
    - Blood samples will also be collected to keep in reserve in the event a sample is lost when shipped or not able to be analyzed when received by the lab to conduct study related testing, and, if you agree, one reserve sample will be used for additional optional biomarker testing in the future

- Urine sample will be collected for urinalysis. Routine laboratory testing will be performed to help assess your general health status.
- You will have a blood or urine pregnancy test if you are a woman who is able to become pregnant.

Week 2 (compensated NASH cirrhosis patients only)
You are allowed to eat prior to coming to this visit**. *You will be asked to take your study drug 4 to 6 hours prior to your study visit and you need to record the time when you took your study drug prior to the visit.***

The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- A blood sample will be taken to check the amount of study drug in your blood. This will be performed approximately 4 to 6 hours after your morning dose of study drug which you took at home before coming for your visit.
- A calculation of the degree of liver impairment present (Child-Pugh Classification).
- A 12-lead electrocardiogram (ECG) will be performed approximately 4 to 6 hours after your morning dose of study drug.
- Your study doctor will discuss with you the possibility of decreasing your study drug dose.

Week 4
The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- A 12-lead electrocardiogram (ECG) will be performed
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood samples will be collected for the following:
    - To check the amount of study drug in your blood
    - To test for alcohol in your blood
- Your study doctor will discuss with you the possibility of decreasing your study drug dose for compensated NASH cirrhosis patients only.

Week 8
You are allowed to eat prior to coming to this visit**. *You will be asked to take your study drug 2 to 6 hours prior to your study visit and you need to record the time when you took your study drug prior to the visit.***

The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- A blood sample will be taken to check the amount of study drug in your blood. This will be performed approximately 2 to 6 hours after your morning dose of study drug which you took at home before coming for your visit.
- A 12-lead electrocardiogram (ECG) will be performed approximately 2 to 6 hours after your morning dose of study drug.

Week 8 (compensated NASH cirrhosis patients only)
You are allowed to eat prior to coming to this visit**. *You will be asked to take your study drug 4 to 6 hours prior to your study visit and you need to record the time when you took your study drug prior to the visit.***

The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- A blood sample will be taken to check the amount of study drug in your blood. This will be performed approximately 4 to 6 hours after your morning dose of study drug which you took at home before coming for your visit.
- 12-lead electrocardiogram (ECG) will be performed approximately 4 to 6 hours after your morning dose of study drug.
- Your study doctor will discuss with you the possibility of decreasing or increasing your study drug dose.

Week 12
The following information will be collected or procedures performed in addition to the general treatment visit assessments:

- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood samples will be collected for the following:
    - To measure biomarkers in your blood
    - To test for alcohol in your blood
    - To determine the state of your liver disease

Week 16
The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- Blood samples will be collected for the following:
    - To check the amount of study drug in your blood
- Magnetic Resonance Imaging – Proton Density Fat Fraction, also known as MRI-PDFF, to image the fat in your liver, and also Magnetic Resonance Elastography, also known as MRE, to measure the stiffness of your liver, and/or Corrected T1 (or cT1) to assess liver inflammation and fibrosis, if you are participating in the MRE part of the study.

Week 20 and Week 28
The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- A 12-lead electrocardiogram (ECG) will be performed
- A blood sample collected to test for alcohol in your blood

Week 24
The following information will be collected or procedures performed in addition to the general treatment visit assessments:

- You will be asked to complete some health-related questionnaires about your daily quality of life and your physical and mental well-being
- A calculation of the degree of liver impairment present (Child-Pugh Classification a) for compensated NASH cirrhosis patients only.
- Blood samples will be collected for the following:

- To check your heart and liver function
- To measure biomarkers in your blood
- To check the amount of study drug in your blood

Weeks 32, 40
All the information and assessments collected during the treatment visits as noted above will be collected at these visits.

Week 36
The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- A 12-lead electrocardiogram (ECG) will be performed
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood sample will be collected for the following:

  - To measure biomarkers in your blood
  - To check the amount of study drug in your blood
  - To test for alcohol in your blood
  - To determine the state of your liver disease

Week 44
The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- Blood samples will be collected for the following:

  - To check the amount of study drug in your blood
  - To test for alcohol in your blood

Week 48
You will be asked about the fasting for this visit and the last time you took the study medication prior to the visit. You will be asked for the last time you took drugs like statins or related lipid lowering medications that may impact the level of cholesterol in your blood.

- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood sample will be collected for the following:

  - To determine the state of your liver disease

Week 52
The following information will be collected, or procedures performed in addition to the general treatment visit assessments:

- You will be asked to complete some health-related questionnaires about your daily quality of life and your physical and mental well-being
- A 12-lead electrocardiogram (ECG) will be performed
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- You will have a Dual-energy x-ray absorptiometry (DXA) scan scheduled at or near the time of the Week 52 visit - this is a scan that uses x-ray beams passing through your bones to measure how healthy they are.
- Fibroscan - This assessment is not required as part of the protocol, but when performed as part of pre-screening or screening visit, a Fibroscan at Week 52 should be performed for analysis. Your study doctor will discuss with you if this test needs to be completed.
- Blood samples will be collected for the following:

    - To check your heart and liver function
    - To measure biomarkers in your blood
    - To check the amount of study drug in your blood
    - To test for alcohol in your blood

- You will have a Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF) within 10 days before the Week 52 visit while you are still on study drug to image fat in your liver and may have a Magnetic Resonance Elastography (MRE) study to measure the stiffness of your liver, and/or Corrected T1 (or cT1) to assess liver inflammation and fibrosis, if you are participating in the MRE part of the study.

Week 56 Follow Up Visit (at 28 ±3 Days after Week 52)
The following information will be collected, or procedures performed:

- A physical examination will be done which will include vital signs, height, weight, body mass index (BMI), waist circumference, waist-hip ratio, temperature, respiratory rate, resting pulse, and seated blood pressure
- You will be asked to list all the medication that you are taking, including all medicine prescribed by a doctor and those that you bought on your own without a doctor’s prescription (herbals and over-the-counter medication).
- You will be asked about your alcohol consumption and how much you drink.
- The study doctor or study staff will ask you about how you have been feeling since your last appointment.
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.

- Blood will be collected after a 10 hour fast (no food or beverages other than water permitted) for the following tests:

    - Blood samples will be taken to check your blood counts (numbers of different types of cells in your blood) and for other laboratory tests to check your general health status (blood's ability to clot, heart, liver and kidney function, status of thyroid gland, blood lipid and sugar levels)

Unscheduled Visits

- In addition to the study visits noted above, there is a possibility that an unscheduled visit could be needed to allow for repeat blood tests or safety checks if required by your study doctor. Your study doctor will inform you if you need to come into the clinic for an unscheduled visit during the study.

Early Termination

If you should leave the study early for any reason the following information will be collected, or procedures performed in addition to the general treatment visit assessments which are performed at all visits according to when you were enrolled in the study:

- You will be asked to complete some health related questionnaire about your daily quality of life and your physical and mental well-being
- A 12-lead electrocardiogram (ECG) will be performed
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood samples will be collected for the following:

    - To check your heart and liver function
    - To measure biomarkers in your blood
    - To test for alcohol in your blood

- If you have been in the study for at least 8 weeks and had imaging tests performed at the Baseline Visit or for at least 24 weeks and had imaging tests performed at the Week 16 Visit:

    - You may have a Magnetic Resonance Imaging – Proton Density Fat Fraction also known as MRI-PDFF - a test that takes images of fat in your liver, and/or Magnetic Resonance Elastography, also known as MRE – a test that measures the stiffness of your liver, and/or Corrected T1 (or cT1) to assess liver inflammation and fibrosis, if you are participating in this part of the study. This test may be performed up to two weeks before your Early Termination visit.

- A Fibroscan will be performed, particularly if you have had a pre-screening or baseline screening Fibroscan. Your study doctor will discuss with you if this test needs to be completed.
- You will have a Dual-energy x-ray absorptiometry (DXA) scan - this is a scan that uses x-ray beams passing through your bones to measure how healthy they are.

If you withdraw your consent and decide to discontinue participation from the study before its planned completion. There will be no penalty or loss of benefits to which you are otherwise entitled. You will be asked to continue with all study visits and procedures, and in particular, agree to safety monitoring and the collection of clinical outcomes information for the duration of the study. In the event that you do not want to attend study visits but are willing to provide health information then you agree to be contacted by letter or telephone or other means of communication to provide important information on your health status. Your study doctor may also review your medical chart after your withdrawal from the study to obtain information about your medical course or laboratory results.

Your study doctor or sponsor may also decide that you should withdraw from participating in the study without your consent if it is in your best interest or if you do not follow the instructions you receive for taking part in the study or if the study is canceled by the FDA or the sponsor. Your study doctor and you will talk about the reason(s) you should no longer participate and decide whether continuing to attend study visits or being contacted by letter or telephone or other means of communication to monitor your health status and get information about clinical events is possible and something you are willing to do.

Early Termination Follow Up Visit (28 ±3 Days after Early Termination Visit)
The following information will be collected, or procedures performed:

- A physical examination will be done which will include vital signs, height, weight, body mass index (BMI), waist circumference, waist-hip ratio, temperature, respiratory rate, resting pulse, and seated blood pressure.
- You will be asked to list all the medication that you are taking, including all medicine prescribed by a doctor and those that you bought on your own without a doctor’s prescription (herbals and over-the-counter medication).
- You will be asked about your alcohol consumption and how much you drink.
- The study doctor or study staff will ask you about how you have been feeling since your last appointment.
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood will be collected after a 10 hour fast (no food or beverages other than water permitted) for the following tests:

- Blood samples will be taken to check your blood counts (numbers of different types of cells in your blood) and for other laboratory tests to check your general health status (blood's ability to clot, heart, liver and kidney function, status of thyroid gland, blood lipid and sugar levels),

Early Termination Follow Up Visit (3 Months ±1 Week after 28-day Early Termination Visit)
This visit is only required for patients who discontinue or leave the study early at or before the Week 36. The following information will be collected, or procedures performed:

- A physical examination will be done which will include vital signs, height, weight, body mass index (BMI), waist circumference, waist-hip ratio, temperature, respiratory rate, resting pulse, and seated blood pressure.
- You will be asked to list all the medication that you are taking, including all medicine prescribed by a doctor and those that you bought on your own without a doctor's prescription (herbals and over-the-counter medication).
- You will be asked about your alcohol consumption and how much you drink.
- The study doctor or study staff will ask you about how you have been feeling since your last appointment.
- A calculation of the degree of liver impairment present (Child-Pugh Classification) for compensated NASH cirrhosis patients only.
- Blood will be collected after a 10 hour fast (no food or beverages other than water permitted) for the following tests:

    - Blood samples will be taken to check your blood counts (numbers of different types of cells in your blood) and for other laboratory tests to check your general health status (blood's ability to clot, heart, liver and kidney function, status of thyroid gland, blood lipid and sugar levels)

Blood Draws
The total amount of blood that will be drawn from you during this time is about 970 mL (approximately 4 cups) and about 1,007 mL (approximately 4 cups) for compensated NASH cirrhosis patients. For comparison, this would be about the same amount given if you did a standard blood donation (480 mL or two cups) two times in one year.

The volume of blood to be drawn at each visit is as follows:

- Screening Visit: about 9 teaspoons (44 mL) of blood
- Baseline Visit: about 16 teaspoons (79 mL) of blood
- Week 2 (compensated NASH cirrhosis subjects only): about 7 teaspoons (37 mL) of blood
- Weeks 4, 8 and 48: about 12 teaspoons (59 mL) of blood at each visit

- Week 12: about 13 teaspoons (65 mL) of blood
- Weeks 16, 44 and 56: about 10 teaspoons (50 mL) of blood at each visit
- Weeks 20, 28, 32, and 40: about 9 teaspoons (44 mL) of blood at each visit
- Week 24, 36, and 52: about 15 teaspoons (73 mL) of blood at each visit
- Follow-up Visit (28 days): about 7 teaspoons (36 mL) of blood
- Follow-up Visit (3 months): about 5 teaspoons (24 mL) of blood
- Early Termination Visit (only for patients who withdrawal from the study early): about 15 teaspoons (73 mL) of blood at each visit

There is also the possibility that the study doctor may collect additional blood samples to perform safety checks. Your study doctor will let you know if and when additional blood samples may need to be collected.

POTENTIAL RISKS, SIDE EFFECTS, DISCOMFORTS, INCONVENIENCES

Possible Side Effects of Resmetirom, Risks or Discomforts

The study drug may cause side effects or other problems. The researchers will be checking your medical information during the study to watch for side effects. However, you should tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects. You may experience none or some of the side effects listed below. There may be other side effects or risks that are not yet known.

The most common side effects (occurring in at least 10% of patients) reported in the Phase 2 studies (MGL-3196-05, MGL-3196-05 (Extension) and MGL-3196-06) were the following:

- Gastrointestinal complaints such as mild diarrhea (25.3%), abdominal discomfort (12.3%) and nausea (20.3%), more often at the start of therapy
- Mild Headache (12.9%)

You will be monitored for the duration of your time in the study and you should tell your study doctor about any changes in your health while taking part in the study.

Placebo Side Effects

The placebo drug looks like the investigational drug, resmetirom, but does not contain any of the active ingredients of resmetirom. In studies conducted, the reported side effects occurring in at least 10% of patients showed that there was no difference in patients treated with resmetirom compared with patients treated with placebo except for gastrointestinal complaints such as mild diarrhea, abdominal discomfort, or nausea.

Procedures

Some procedures that will be done during the study may carry some risks, these are given below, and your study doctor can provide more information to you.

Procedure	Risk
Blood sample	Blood samples will be taken during the study. Using a needle to remove blood from a vein is called "a blood draw." It may be necessary to try more than once to draw blood. A new needle will be used for each blood draw. You might feel pain or be light-headed from this. You may have the following at the site of the needle stick when blood is drawn: • Additional bleeding at the site of the blood draw • Temporary discomfort • Bruising • Infection (rarely).
ECG	Electrocardiograms (ECGs) will be done during this study. ECG is a test that records the heart's electrical activity. During an ECG, electrode patches/sensors are applied to the chest area, as well as your arms and legs. • The sticky pads placed on your chest may cause skin irritation • The stickiness from the pads also may cause some hair to be removed when the pads are taken off
Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF) Corrected T1 (cT1) Magnetic Resonance Elastography (MRE)	MRI does not use any radiation. MRI is a safe and pain free test done to produce detailed pictures of your body's organs and structures. During the MRI and/or cT1 scan, you may feel confined due to the small opening in which you are placed for the scan. MRI machines are very noisy and ear protection may be worn at all times. MRI does not hurt but it requires you to hold still for a considerable amount of time. If you experience the feeling of being confined or unable to hold still, you may need medication to make you feel comfortable. Your doctor will explain the risks of those medications. During the MRE, you may feel vibrations from the paddle attachment on your skin. You will be asked to hold your breath at least four times during the MRE scan. Each breath hold will last about 15 to 20 seconds. • Magnetic resonance imaging uses a strong magnetic field, which is not harmful by itself, but implanted medical devices that contain metal may malfunction or cause problems during an MRI, cT1, and/or MRE exam.

	• If you have any implanted devices such as a pacemaker, please inform the doctors before the procedure. • Metal is also not allowed in an MRI machine, so please let the doctors know if you have any metal in your body. • Some people may feel claustrophobic during this procedure. Please let the study team know if you have experienced fear of small or narrow spaces before having the MRI study. • You will also be required to fast for this procedure. This may cause distress and if you are diabetic your sugar levels may go down.
DXA Scan	DXA is a type of scanner that measures bone density. It uses a small amount of radiation to produce pictures of the inside of your body. The amount of radiation used is extremely small—less than one-tenth the dose of a standard chest x-ray, and less than a day's exposure to natural radiation. There is always a slight chance of cancer from excessive exposure to any radiation. • The radiation you would receive is minimal. • Radiation may increase the risk of cell changes in your body or having cancerous tumors. It is not expected to greatly increase these risks but the exact increase in such risks is unknown.
Fasting	You will be asked to fast for 10 hours before most of your visits to the study site. • Could cause dizziness, headache, stomach discomfort or fainting • If you are diabetic this may cause your blood sugar to drop significantly.
FibroScan	• The risk is minimal. This can include pressure from the probe as well as the risk associated with fasting for the procedure.

Pregnancy

As the Sponsor does not know the effect of the study medicine on an unborn baby, you or your partner should not become pregnant during the study or for 30 days after you have stopped taking the study medicine. The effects of study medicine on a nursing infant are unknown. If you are pregnant or breastfeeding, you cannot participate in the study.

If you are capable of becoming pregnant then in order to prevent a pregnancy during the study, you and your partner must agree to use one of the following methods of birth control:

- Not having sexual intercourse
- Using hormonal contraception such as the combined oral contraceptive pill, a vaginal ring or an injectable, implantable or intrauterine device
- Using hormonal contraception (as described above) and a barrier method, such as a condom

You should continue to use the birth control described above for 30 days after you have stopped taking the study medicine.

If you are male and are sexually active with a female partner who can become pregnant, you must either be sterile (vasectomy with history of a negative sperm count at least 90 days following the procedure), practice total abstinence from sexual intercourse as the preferred lifestyle (periodic abstinence is not acceptable), use a male condom with any sexual activity, or agree to use a birth control method considered to be appropriate (such as one of the methods identified above for female subjects who are capable of becoming pregnant) from the time of Screening until 30 days after you have stopped taking the study medicine. Male patients must agree not to donate sperm for a period of 30 days after you have stopped taking the study medicine.

If you (or your partner) become pregnant during the study, you must tell your study doctor immediately. If you (your partner) agree, the Sponsor would like to follow-up on the outcome of your (your partner's) pregnancy including information regarding health, the date of conception, the course of the pregnancy, the medical treatments you may receive and health of your baby following birth.

POTENTIAL BENEFITS

If you receive resmetirom it might help your NASH/NAFLD, improve your LDL-cholesterol other fats in your blood, reduce the fat in your liver and ultimately reduce your risk from heart or liver disease, but there is no guarantee that this study will help you. You may learn more about NASH/NAFLD while you are in this study. The information that is collected from the study may help researchers find new treatments for future patients.

GENETIC, BIOMARKERS AND RESERVE SAMPLES

If you agree, a sample of your blood will be collected to look at your genes, which are also called DNA. Genes are in the cells which are present in your blood. Genes are what you inherit within your family. Some genes control the color of your eyes or the color of your hair, other genes might make you more likely to get certain diseases or affect whether medication helps you and/or gives you side effects.

If you agree, the optional genetic testing in this study will be done to look at genes that cause NASH or other specific genes which will help to understand the effects of resmetirom (study drug). By looking at certain genes, the Sponsor might also be able to improve how the study drug is used in the future. The Sponsor will not check all your genetic material and is not exploring genes that might result in chance findings of particular diseases.

No other tests will be performed without your consent. No one other than the sponsor (and/or people or companies working with the Sponsor) will test your samples. You will not receive the results of the genetic testing. Individual results will also not be presented to your doctor or your family members; the results will remain the property of the Sponsor.

A sample of your blood will also be collected for potential biomarker analysis. Biomarkers are substances in your body that can be used to detect a disease, describe it, or find out how a disease is responding to treatment. Biomarkers may be made of DNA, RNA, proteins, cells, or parts of cells.

A blood sample will be collected at each visit to keep in reserve at the lab in the event the primary sample is lost in transit to the lab, or not able to be analyzed when received by the lab for study related testing. If you agree, one reserve sample will be retained and used for future biomarker testing.

Your samples will be handled in a manner that protects each subject's privacy and confidentiality by using a unique number. The information which comes from your samples will be stored using this number. The reserve samples may be kept by the sponsor in a facility approved by the sponsor for as long as the sample(s) are useful for scientific research which may be for many years (no time limit). The facility may be in a different country from where you have provided the samples.

You may withdraw your consent for the use of one of your reserve samples for future biomarker testing at any time with no penalty or loss of benefits to which you are otherwise entitled. You can withdraw your consent by making a request to the investigator. In this case, any remaining samples will be destroyed, but information already available will continue to be used in order to keep the results accurate and complete.

The non-physical risk in this study is the possible loss of confidentiality related to the results of genetic testing on your samples. The sponsor and others involved in this study will make every effort to make sure no one gets your test results except those people or companies you read about in this form. You must judge for yourself whether learning more about differences in genes among people and how it relates to health and disease are more important than this risk and any other potential future risks.

There are also current limited protections provided to you by a US Federal law, the Genetic Information Nondiscrimination Act (GINA), which generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against people based on their genetic information. All health insurance companies, group health plans, and all employers with 15 or more employees must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it prohibit discrimination on the basis of a genetic disease or disorder that you already know about.

COMPENSATION
You will receive a travel stipend of $75 for each visit where you have to come to the office as well as a $50 stipend for each MRI. You will be paid following each visit.

EXPENSES
It is not expected to cost you to participate in the study. The study medicine(s) will be provided to you free of charge and you will not be charged for any procedure performed for this study.

The Sponsor has a contract with the study doctor/study site who will receive payment for taking part in this study.

INSURANCE AND SUBJECT INJURY
In the event that you suffer any illness or injury (including a research-related injury) during the course of the study, any associated medical expenses will be your responsibility and/or the responsibility of your non-governmental medical insurance provider or non-governmental third-party payer in the ordinary manner. In this regard, you agree to cooperate in the claims process for your insurance or other third-party payer for any such injury. However, if you have governmental medical insurance or if your non-governmental medical insurance provider or third-party payer does not pay for all of the costs to treat these research-related injuries, the sponsor will pay for the unpaid costs for the reasonable and necessary treatment of your injuries directly caused by resmetirom or study procedures performed on you that would not have been performed if you did not participate in the study. No other funds are readily available for payment related to your injuries. You are not waiving any of your legal rights or releasing anyone from liability for negligence by signing this document. In the event you believe you have been injured or become ill as a result of the study you should immediately contact the Study Doctor. The study doctor will make sure you get medical care for your injury or illness.

VOLUNTARY PARTICIPATION/WITHDRAWAL
You can choose whether you want to take part in the study, and you can change your mind at any time. If you decide not to take part or stop taking part in the study after it

has started, this will not affect your future treatment and care. There will not be any penalty or loss of benefits to which you are otherwise entitled. If you want to withdraw from the study, you should contact your study doctor or study site staff using the contact information found on the first page of this document.

The Sponsor, Ethics Committee or Regulatory Authority (such as the FDA) may also decide to stop the study at any time for any reason.

If there is new information available on the study medicine during the study which might make you change your mind about taking part in the study, you will be informed of this new information without delay.

ALTERNATIVE TREATMENTS
Weight loss with diet and exercise has been shown to be helpful in some patients with NASH.

There are currently no approved treatments that are specifically designed to treat NASH, liver fibrosis (scarring) or cirrhosis.

There are other medications that may improve your LDL cholesterol and your triglyceride level such as statins or fish oils.

Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS RESEARCH?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888)-303-2224 or (800) 562-4789, irb@cgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

CONFIDENTIALITY AND DATA PROTECTION
Madrigal Pharmaceutical Inc. (the Sponsor) Four Tower Bridge, 200 Barr Harbor Drive, West Conshohocken, PA 19428, is responsible for all the personal data collected from

you during the study and for making sure all those working on the study comply with any data protection requirements for the collection, use and processing of personal data collected for this study.

The Sponsor is responsible for deciding what personal data needs to be collected during the study and how this data will be used. Your study doctor and study site staff will be responsible for collecting personal data, as required, for you to take part in the study. Along with medical data (including data from laboratory samples), other data collected may include your sex, age or date of birth, ethnicity, body weight and height. Your personal data related to your participation in the study will be replaced by a code so that you cannot be identified directly. Only your study doctor and study site staff will be able to identify you from the code. The Sponsor and the other companies working with the Sponsor on the study (the Sponsor representatives) will not be able to identify you directly. The Sponsor and their representatives will be responsible for processing the information which will be stored under the code allocated to you and are responsible for ensuring your data remains confidential as required by the law in your country. Your personal data held by the Sponsor or their representatives will be stored for up to 25 years after the study has ended.

Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Some authorized Sponsor representatives (including the contract research organization (CRO) working with the Sponsor, labs testing your samples), National Health Authorities (such as the FDA), Independent Review Board (IRB) will have limited access to your personal information (medical records) held by the study site when required to check that study procedures have been performed and data has been captured correctly, but the information will remain confidential as required by the law in your country.

If the Sponsor makes public any study results your identity will remain confidential.

You have certain rights to access your personal data collected and held and to have any inaccuracies corrected. In certain circumstances you can request that the use of your personal data is limited or to have your personal data erased, however, the Sponsor may be required to keep certain data until after the study has been completed. You may exercise these rights by applying in writing to the Sponsor. You may do this by making the request through the Study Doctor. They will then pass the request on to the Sponsor. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study. If you decide to no longer take part in the study no further personal information will be collected unless you have a side effect related to the study. Any personal information collected up to the point of your withdrawal from the study would need to be retained and used as it forms part of the study data. If you withdraw from the study but

do not withdraw your Authorization, new health information may be collected until this study ends.

All reasonable measures to protect the confidentiality of your study records and your identity will be taken to the extent permitted by the applicable laws and/or regulations and will not be made publicly available. HIPAA (Health Insurance Portability and Accountability Act) Regulations or applicable state law requires that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, the Institution and the Sponsor. In order to analyze the data collected during this research study, all of the health information generated or collected about you during the study may be inspected by the study Sponsor or the authorized agents of the Sponsor, the FDA (U.S. Food and Drug Administration), the Department of Health and Human Services (DHHS), other government regulatory agencies from other countries, the IRB, as well by representatives of Madrigal Pharmaceuticals, Inc. or their designee PRA Health Science.

The sponsor and the groups above will use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research

Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

The results of this study may be presented at meetings or in publications. However, your identity will not be disclosed in these presentations. By signing the informed consent form, you are authorizing such access to your medical records.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin, this authorization will expire on 31Dec2060.

There is no expiration of this authorization except for research conducted in the states listed above.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

There is a risk of loss of confidentiality in research studies. Every effort will be made to protect you and your health information to the extent possible.

PATIENT INFORMED CONSENT FORM

I have received information about the medical research study and have had the opportunity to read the information and to ask questions and have received answers.

I voluntarily consent to:

- Participate in the study
- To follow the instructions provided by my study doctor
- The processing of my personal data derived from the study
- The transfer of my personal data to countries outside of my own where data protection might differ from the data protection in my country
- The Sponsor and its representatives, as well as Regulatory Authorities, to compare data reported in the study to those contained in my medical records. I consent to this under the condition that the information obtained is not disclosed.
- The use and disclosure of my personal health information.

I consent to participate in the blood draw to measure how my genes (e.g., genetic testing) are related to the disease and the response to the study drug. Initial below:

_____ I agree _____ I do not agree

I consent to having one of my reserve samples retained and used for future biomarker testing. Initial below:

_____ I agree _____ I do not agree

I consent to participate in the MRI-PDFF to measure the amount of fat in my liver, if this procedure is available at my site and I am able. Initial below:

_____ I agree _____ I do not agree

_____Not Applicable

I consent to participate in the MRE imaging to measure the stiffness of my liver if this procedure is available at my site and I am able. Initial below:

_____ I agree _____ I do not agree

_____Not Applicable

I consent to participate in the cT1 imaging to assess liver inflammation and fibrosis if this procedure is available at my site and I am able. Initial below:

_____ I agree _____ I do not agree

_____Not Applicable

If for any reason I want or need to stop taking the study medicine before my final study visit, I consent to continue with all study visits and procedures, and in particular, agree to safety monitoring and the collection of clinical outcomes data for the duration of the study. Initial below:

_____ I agree _____ I do not agree

If for any reason I want or need to stop taking the study medicine before my final study visit and am not willing to continue with all study visits, I consent to be contacted by letter or telephone or other means of communication to provide important information on my health status. Initial below:

_____ I agree _____ I do not agree

I know that at any time and without giving any reason I can withdraw my consent and stop taking part in the study. This will not affect my future treatment and care.

I will receive a signed and dated copy of this Patient Information Sheet and Informed Consent Form for my records.

Signatures

Patient	
	Print name
Signature	Print date

Statement of Study Personnel Performing Consent
I have explained the consent in language the patient understands.

	Print name
Signature	Print date

Statement of the Witness (when applicable*)
The information in the consent was accurately explained to, and appeared to be understood by the subject. Consent was freely given.

Impartial Witness	
	Print name
Signature	Print date

*Impartial Witness: If the patient cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.